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1646

PATENT/Docket No.: 10012-006510US

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CERTIFICATE OF MAILING (37 CFR 1.8)
Date of Deposit with U.S. Postal Service: July 8, 2004

I hereby certify that this transmittal, together with the appeal brief referred to below, is being deposited with the United States Postal Service as first class mail under 37 CFR 1.8 on the date indicated above and is addressed to Mail Stop Appeal Brief - Patents, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Karen Karlin

Karen Karlin

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS

Art Unit		1646
Examiner		Li, Ruixiang
Applicant(s)	:	Christopher D. Creech et al.
Application No.:		09/927,267
Filed	:	August 10, 2001
For	:	CNG2B: A NOVEL HUMAN CYCLIC NUCLEOTIDE-GATED ION CHANNEL

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF UNDER 37 CFR 1.192

Sir:

Appellant hereby transmits three (3) copies of the brief required under 37 CFR 1.192 in connection with the appeal in the above-captioned application. The NOTICE OF APPEAL UNDER 37 CFR 1.191 was filed on March 16, 2004, and received by the Patent and Trademark Office on March 19, 2004.

Appellant hereby requests that the fee for filing a brief in support of an appeal, $165.00 (small entity), or such greater or lesser amount as the Commissioner may deem is required by 37 CFR 1.17(f), be charged to Deposit Account No. 20-1430.

[X] The brief is being filed under 37 CFR 1.8 and the required Certificate of Mailing appears above.

[ ] Appellants hereby request an oral hearing pursuant to 37 CFR 1.194 and hereby request that the fee for filing a request for oral hearing, $145.00 (small entity), or such greater or lesser amount as the Commissioner may deem is required by 37 CFR 1.17(g), be charged to Deposit Account No. 20-1430.

[X] Appellants reserve the right to request an oral hearing pursuant to 37 CFR 1.194 following receipt of the Examiner's Answer.

[X] A Petition to Extend Time for two months from May 16, 2004 to July 16, 2004 is enclosed.

Respectfully submitted,

TOWNSEND and TOWNSEND and CREW LLP

Date: July 8, 2004

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Enclosures: Appellant's Brief Under 37 C.F.R. 1.192 (in triplicate)
Pet. to Extend Time SB/22 with fee authorization (in duplicate)
Fee Trans. SB/17 with fee authorization (in duplicate)

PATENT
Atty. Docket No.: 018512-006510US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No. 6230
CREECH et al.	Examiner: Li, Ruixiang
Application No.: 09/927,267	Technology Center/Art Unit: 1646
Filed: August 10, 2001	
For: CNG2B: A NOVEL HUMAN CYCLIC NUCLEOTIDE-GATED ION CHANNEL	APPELLANT'S BRIEF UNDER 37 C.F.R. 1.192
Customer No.: 20350	

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This brief is filed in triplicate pursuant to 37 C.F.R. §1.192(a), following the Notice of Appeal, mailed March 16, 2004. A petition to extend time to submit the Appeal Brief for two months, from May 16, 2004, to July 16, 2004, is filed herewith. Also submitted in triplicate with this brief is authorization to pay the fee as set forth in 37 C.F.R. §1.17(c).

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I. REAL PARTY IN INTEREST

The real party in interest in U.S. Application No. 09/927,267 is ICAgen, Inc.

II. RELATED APPEALS

Appellant is currently appealing the PTO's rejection of the claims in USSN 09/767,597, 09/548,933, and 09/623,304. The results of these appeals, which relate to the standard of assessing utility under 35 U.S.C. §101, will directly affect the decision by the Board of Patent Appeals and Interferences in this pending appeal.

III. STATUS OF THE CLAIMS

Claims 1-40 were originally filed. Claims 2, 4-7, 9-18 and 21-40 have been canceled. Claims 1, 3, 8, 19, and 20 are pending in the present application. In the final Office Action mailed September 16, 2003, and the Advisory Action mailed May 11, 2004, the Examiner rejected claims 1, 3, 8, 19, and 20 under 35 U.S.C. §101, alleging lack of a credible specific and substantial utility. The Examiner also rejected all pending claims under 35 U.S.C. §112, first paragraph, alleging failure to enable the claimed invention based on the utility rejection.

IV. SUMMARY OF THE INVENTION

The invention relates to the first isolation and characterization of CNG2B, a member of the CNG family of polypeptide subunits of cyclic nucleotide gated cation channels that is expressed primarily in the central nervous system (CNS). The instant application provides both the nucleotide and amino acid sequences of human CNG2B, as well as methods of assaying for modulators of cation channels comprising a CNG2B subunit, antibodies to CNG2B polypeptides, and methods of detecting CNG2B nucleic acids and polypeptides.

The pending claims are directed to an isolated nucleic acid that encodes a polypeptide comprising a subunit of a cation channel. The polypeptide has the following attributes: (i) it forms, with at least one cyclic nucleotide gated cation channel (CNG) alpha subunit, a cation channel having the characteristic of cyclic nucleotide-gating; and (ii) it comprises an amino acid sequence of SEQ ID NO:1.

V. ISSUES ON APPEAL

1. The rejection for lack of utility is improper because the present invention meets the statutory requirement and because the Examiner has not properly established that the asserted utilities are not credible, specific, and substantial.

2. The rejection for lack of enablement is improper because the present invention does not lack utility.

VI. CLAIM GROUPING

Claims 1, 3, 8, 19, and 20 stand and fall together.

VII. ARGUMENT

A. The Rejection for Lack of Utility Is Improper

Claims 1, 3, 8, 19, and 20 stand rejected under 35 U.S.C. §101 because the Examiner alleges that the claimed invention lacks either a well-established utility or a credible specific and substantial asserted utility.

Appellant respectfully traverses this rejection and argues that the rejection is improper. The present invention resides in the identification of human CNG2B nucleic acids. Utility under 35 U.S.C. §101 is present because the identification of CNG2B nucleic acids permits one of skill in the art to screen for agonists or antagonists of the cation channels comprising a CNG2B subunit, which can be used, *e.g.*, for treating neurological disorders related to altered olfactory sensory signal transduction.

1. Standard to Assess Utility

According to MPEP §2107, the Examiner should review the claims and the supporting written description to determine whether the utility requirement under 35 U.S.C. §101 is met. No rejection based on lack of utility should be made if an invention has a well-established utility, *i.e.*, a utility that will be immediately appreciated by one of ordinary skill in the art based on the characteristics of the invention, regardless any such utility has been asserted. Neither should any rejection be made for lack of utility if an applicant has asserted a specific and substantial utility that would be considered credible by one of ordinary skill in the art.

In most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. §101. MPEP §2107.02 III A. The Court of Customs and Patent Appeals stated in *In re Langer*:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of §101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 183 USPQ 288, 297 (CCPA, 1974, emphasis in original). To overcome the presumption of sufficient utility as asserted by an applicant, the Examiner must carry the initial burden to make a *prima facie* showing of lack of utility and provide a sufficient evidentiary basis for the conclusion. In other words, the Examiner "must do more than merely question operability--[he] must set forth factual reasons which would lead one skilled in the art to question objective truth of the statement of operability." *In re Gaubert*, 187 USPQ 664, 666 (CCPA 1975).

MPEP §2107.02 IV further states, a detailed explanation should be given for a utility rejection as to why the claimed invention has no specific and substantial asserted utility. Documentary evidence should be provided when possible. Otherwise the Examiner should specifically explain the scientific basis for his factual conclusions.

Moreover, the MPEP states that once the examiner presents a *prima facie* case of unpatentability for lack of utility, the burden of coming forth with evidence or arguments shifts to the applicant. After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record and by a preponderance of evidence with due consideration to persuasiveness of argument. "If the record as a whole would make it more likely than not that the asserted utility for the claimed invention would be considered credible by a person of ordinary skill in the art, the Office cannot maintain the rejection." MPEP §2107.02 VI.

2. The Asserted Utility and the Examiner's Rejection

The instant application asserts a specific and substantial utility of the claimed invention. For example, it is asserted on page 7, lines 12-14, and on page 9, lines 24, to page 10, line 7, of the specification that the identification of CNG2B nucleic acids and polypeptides allows screening for modulators of CNG2B channels using *in vitro* or *in vivo* assays. On page 62, line 20, to page 63, line 15, it is further asserted that human CNG2B and rat OCNC2 are orthologs as they share a high level (greater than 93%) of amino acid sequence identity and demonstrate a similar expression pattern. The modulators of CNG2B channels are thus useful for treating neurological disorders such as those involving abnormal olfactory signaling, as rat OCNC2 is known to participate in olfactory transduction.

Appellant has in addition submitted a declaration pursuant to 37 C.F.R. §1.132 by Dr. Zhixin Lin, a Program Scientist at ICAgen, Inc. (submitted with Appellant's communication to the PTO on March 16, 2004), to establish the physiological function of the human CNG2B cation channel and the therapeutic use of its modulators.

In the Office Action mailed July 11, 2002, the Examiner alleges that the instant specification fails to establish a specific and substantial asserted utility of the claimed invention. In addressing Appellant's assertion that human CNG2B is the ortholog of rat OCNC2 and thus has similar biological function in olfactory signaling, the

Examiner contends that even with a greater than 93% amino acid sequence identity between human CNG2B and rat OCNC2, no utility under 35 U.S.C. §101 is established because "the instant disclosure fails to provide any experimental data or information on whether the claimed CND2B protein functions like a cyclic nucleotide-gated channel and determination/confirmation of the biological functions or activities of CNG2B requires significant further research" (the bridging paragraph between pages 3 and 4 of the Action mailed July 11, 2002). The Examiner offers the reference by Finn *et al.* to demonstrate the diversity of the cyclic nucleotide gated ion channels, and the references by Bork and Koonin and by Ji *et al.* to argue the lack of reliability in predicting protein function based on amino acid sequence homology.

In the Office Action mailed April 8, 2003, the rejection for lack of utility is maintained. The Examiner reiterates that the specification has not provided evidence to support the asserted biological functions of the human CNG2B channels. In response to Appellant's argument distinguishing fact patterns of the present case and the cited references, the Examiner simply states, "they (human CNG2B and rat OCNC2) are still not the same molecule[]," and offers no further documentary evidence or scientific reasons to support his conclusion (the bridging paragraph between pages 3 and 4 of the Action mailed April 8, 2003).

In the Final Office Action mailed September 16, 2004, the utility rejection is sustained from the previous Actions. The Examiner questions Appellant's assertion of human CNG2B channel's physiological function and association with olfactory signaling, yet again does not give any specific evidence or objective reason why the asserted utility based on human CNG2B-rat OCNC2 comparison is not credible (the third full paragraph on page 3 of the Final Office Action). The Examiner also contends that the asserted utility is not specific, because the "disease condition," *i.e.*, altered olfactory signal transduction, and the "biological activity," *i.e.*, the opening and closing of CNG cation channels, are too ambiguous (the first full paragraph on page 4 of the Final Office Action). The Examiner further contends that the asserted utility is not substantial,

because no specific biological or physiological function of human CNG2B or specific disease condition associated with human CNG2B is disclosed (the bridging paragraph between pages 4 and 5 of the Final Office Action).

In the Advisory Action mailed May 11, 2004, the Examiner again maintains the utility rejection, alleging that the specification does not disclose a specific and substantial utility.

3. The Claimed CNG2B Polynucleotides Are Useful for Screening of Compounds for Treating Olfactory Sensory Disorders

As described in the present application, the present inventors cloned, for the first time, the human polynucleotide sequence encoding CNG2B, a cyclic nucleotide gated cation channel. The inventors also identified the amino acid sequence of CNG2B and determined the tissue-specific expression pattern of CNG2B.

It is well known in the art that rat OCNC2 is highly expressed in the brain and capable of forming homomultimeric and, with OCNC1 alpha subunits, heteromultimeric, cyclic nucleotide gated cation channels involved in olfactory signal transduction (*see* Bradley *et al.*, *Proc. Natl. Acad. Sci. USA* **91**:8890-8894 (1994), submitted as Reference A in the Information Disclosure Statement filed June 11, 2002). Human CNG2B is also highly expressed in the brain, and its amino acid sequence shares a greater than 93% sequence identity with that of the rat OCNC2 (Figure 1 and page 62, line 20, to page 62, line 15, of the present application and Bradley *et al.*). In addition, Dr. Lin indicates in her declaration that based on the disclosure of the present specification and the general knowledge in the art, a skilled artisan would believe that human CNG2B is orthologous to rat OCNC2 and that a CNG2B channel functions in mediating olfactory transduction (paragraph 7 of Dr. Lin's declaration).

Because one of skill in the art would expect the CNG2B channel to play a physiological role in olfactory signaling, it would therefore be apparent to an artisan that CNG2B can be an excellent therapeutic target for modulating olfactory transduction

using CNG2B channel openers or blockers. Compounds capable of modulating CNG2B activity can be used for treating conditions and disorders caused by olfactory sensory anomaly (paragraph 8 of Dr. Lin's declaration).

The present application provides nucleotide sequences of human CNG2B, methods of assaying CNG2B channels function, and methods of assaying for compounds increase or decrease ion flux of CNG2B channels. A skilled artisan, after reading the present application, would therefore be able to routinely identify modulators of CNG2B channels and determine if a candidate compound can affect the physiology of olfactory perception by altering CNG2B channel activity.

Appellant thus contends that the asserted utility for the present invention is one supported by the general knowledge in the relevant field of art and that a person of ordinary skill in the art would find such utility credible.

4. The Asserted Utility is Specific, Substantial, and Credible

Appellant maintains that the disclosure of human CNG2B polynucleotide and amino acid sequences, combined with the methods disclosed in the specification and the level of skill in the art, is sufficient to establish a credible specific and substantial utility under the definitions provided by the MPEP.

Specific Utility

Appellant asserts that the present invention has a specific utility. Specific utility is defined by the MPEP as a utility that is specific to the subject matter claimed. The MPEP explains that applications show sufficient specific utility when applicants disclose a "specific biological activity" and reasonably correlate that activity to a "disease condition." MPEP §§2107.01 and 2107.02. In the present application, Appellant identifies the nucleic acid and amino acid sequences of human CNG2B, demonstrates the expression pattern of CNG2B, teaches the recombinant expression of CNG2B, and describes methods for assaying CNG2B channel activity. Appellant further discloses a

"disease condition" (*i.e.*, abnormal olfactory signaling) that correlates with a "biological activity" (*i.e.*, the opening and closing of a CNG2B channel). The application further provides methods for identifying compounds capable of modulating CNG2B channel activity. These compounds can therefore be used, *e.g.*, for treating olfactory sensory disorders related to abnormal ion flux. Appellant thus submits that the present invention has a specific utility, namely that CNG2B channels can mediate cation flux in neuronal cells involved in olfactory transduction, which is clearly specific for the claimed CNG2B channels and not any polypeptide or even just any ion channel.

Substantial Utility

Appellant also asserts that the present invention has a substantial or "real-world" use. This invention provides human CNG2B polynucleotide and amino acid sequences. The application also demonstrates that CNG2B channels modulate cation flux in cells of the central nervous system and teaches how to identify agonists and antagonists of the CNG2B channels. For example, on pages 42-50 of the specification, Appellant provides assays that can be used to test for inhibitors and activators of Slo3 channels, *e.g.*, assays that involve measuring current, measuring membrane potential, or measuring ion flux using various methods in electrophysiology. The present invention therefore has a real-world use in the modulation of olfactory perception, as well as in the identification of compounds that modulate CNG2B channels and thus can be useful as therapeutic agents for treating diseases or conditions related to abnormal neuronal activity in cells involved in olfactory transduction.

Credible Utility

Finally, Appellant contends that the asserted utility of the present invention is credible, *i.e.*, would be believable to one of skill in the art. Appellant submits that an ordinarily skilled artisan, after reading this application, would know (a) how to identify CNG2B channels, (b) how to identify agonists or antagonists of CNG2B channels, and (c) how to use these agonists or antagonists so identified to modulate cation

flux in neuronal cells involved in olfactory signaling. Because of the high level of amino acid sequence identity between human CNG2B and rat OCNC2 and the latter's known involvement in olfactory signaling, one skilled in the art would believe that the identification of the human ortholog of rat OCNC2 is useful for developing new therapeutics for treating disorders caused by abnormal olfactory sensory function (see paragraphs 7 and 8 of Dr. Lin's declaration).

5. The Examiner Has Raised and Maintained the Utility Rejection in a Manner Inconsistent with the MPEP

Credible Utility

Despite the assertion of a specific and substantial utility of the claimed invention in the specification and Dr. Lin's declaration supporting the asserted utility, the Examiner maintains the utility rejection based on personal disbelief of the asserted utility rather than credible scientific evidence. For example, the Examiner states in the July 11, 2002, Office Action that the specification "fails to provide any experimental data or information on whether the claimed CNG2B protein functions like a cyclic nucleotide-gated channel." The Examiner further cites several scientific publications (Finn *et al.*, Bork and Eugene, and Ji *et al.*) to argue that prediction of protein function based on sequence homology is highly unreliable and therefore Appellant's assertion of human CNG2B as the ortholog of rat OCNC2 is not credible (page 4 of the July 11, 2002, Office Action). Appellant specifically addresses these publications in the communication to the PTO filed January 13, 2003, pointing out that these publications caution unreliable functional prediction based on low level of amino acid sequence homology that is also limited to a small region of a protein, which is fundamentally distinguishable from the art-recognized approach of assigning inter-species orthologs based on a high level of overall amino acid sequence identity (pages 4-6 of the communication filed January 13, 2003). In response to Appellant's rebuttal, the Examiner merely reiterates in the Office Action of April 8, 2003, that the application provides no data to prove that CNG2B is a cyclic nucleotide-gated ion channel and that regardless the greater than 93% overall

sequence identity, human CNG2B and rat OCNC2 "are still not the same molecule[]" (the bridging paragraph between pages 3 and 4 of the April 8, 2003, Office Action).

Raising and maintaining a rejection for lack of utility in such a manner is inconsistent with the proper practice described in the MPEP, which places the initial burden on the Examiner, not Appellant, to provide evidence to support a factual conclusion of the credibility of an asserted utility. In fact, MPEP §2107.02 III.B. specifically cautions Office personnel that, once an assertion of a particular utility is made, "that assertion cannot simply be dismissed ..... as 'wrong,' even when there may be reason to believe the assertion is not entirely accurate." Instead, the Examiner must provide an explanation setting forth the reasoning used in concluding that the asserted specific and substantial utility is not credible; support for factual findings relied upon in reaching the conclusion; and an evaluation of all relevant evidence of record, including utilities taught in the closest prior art. MPEP §2107.02 IV. Furthermore, it is stated in MPEP §2107.02 VI that, after the Examiner has provided evidence or objective reasons to question the credibility of an asserted utility, and the applicant has further responded with evidence or argument, "patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument." A utility rejection cannot be properly maintained if the record as a whole indicates it is more likely than not that one of skill in the art would consider the asserted utility credible. Appellant has responded to the Examiner's evidence and objective reasons for holding the asserted utility not credible, *i.e.*, the three papers initially cited in the Office Action of July 11, 2002, by specifically distinguishing the fact patterns and by offering Dr. Lin's declaration; on the other hand, the Examiner has offered no additional evidence, objective reasons, or arguments. Appellant thus submits that when considered together, the record favors a holding of sufficient credibility in the asserted utility.

Specific Utility

As discussed above, a specific utility is specific to the subject matter claimed. MPEP §2107.01 I states that a specific utility "contrasts with a general utility that would be applicable to the broad class of the invention." Several examples are provided in this section for such "general utility," including using a polynucleotide sequence as a gene probe, using a compound for treating an unspecified disease or condition, using a compound for its unspecified biological properties, and the like. These examples are dissimilar to the present invention in that the so-called uses in these examples are essentially applicable to any one particular polynucleotide sequence (which could always be used as a probe) or any given compound (which could potentially have some type of biological activity and may be used to treat some disease or condition). In the present case, however, a far more concrete biological activity and thus a far more specific use are asserted: a functional role in regulating ion flux in neuronal cells of the olfactory and a use for treating altered olfactory transduction. It simply cannot be said that such function or use is applicable to any other protein or even any other ion channel.

In holding the asserted utility non-specific, the Examiner appears to take the position that in order to meet the requirement for a specific utility, an individual disease or condition rather than a class of diseases or conditions (*e.g.*, olfactory sensory disorder) must be named. Appellant contends that this position is unattainable. First and the foremost, the MPEP neither distinguishes such disease "species" and "genus" nor imposes such a requirement. Secondly, in many cases, the distinction between a disease "species" and "genus" can be blurred. For instance, a disease, such as diabetes or breast cancer, that might be regard as an individual disease can be in fact a class of diseases with different underlying causes and therefore different treatment methods. In assessing the utility of the present invention, the Examiner has apparently heightened the standards for a specific utility. Appellant contends that the asserted utility is sufficiently specific under the standard set forth in the MPEP.

Substantial Utility

According to the MPEP, a substantial utility is a "real world" use. "Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities." MPEP §2107.01 I. As Dr. Lin attests in her declaration, given the state of the relevant art, the present disclosure allows an ordinarily skilled artisan to readily identify inhibitors or activators of a CNG2B channel, which can be used to correct or modify the sensory transduction in the olfactory (paragraphs 8 and 9 of Dr. Lin's declaration). The asserted utility of the present invention therefore does not require significant further research and is a "real world" use.

The Examiner repeatedly argues, however, that "the specification fails to define a specific biological function or any physiological significance of the claimed [CNG2B] molecules and fails to specify a specific disease associated with the molecules of the present invention" and that "significant further research is needed to determine the specific biological functions of the molecules of the present invention and to determine any diseases that are involved in the molecules" (*see, e.g.*, the bridging paragraph between pages 4 and 5 of the Office Action mailed September 16, 2003). The Examiner's arguments reflect a personal disbelief of the biological function of CNG2B as asserted by Appellant in the specification and the readily applicable nature of the invention as attested by Dr. Lin in her declaration. Yet this disbelief is not supported by the totality of the record. The Examiner's arguments also reflect a heightened standard for a specific utility, which requires naming individual diseases or conditions. Yet this standard is not the one provided by the MPEP. Appellant contends that a substantial utility has been established by the assertions in the specification and by Dr. Lin's declaration.

In summary, Appellant do not believe that the Examiner has adhered to the proper standards for assessing utility as described in the MPEP. The utility rejection is therefore improper and should be withdrawn.

6. Finding Sufficient Utility in the Present Application is Consistent with the Policy of Encouraging Early Disclosure

Our patent law places much emphasis on encouraging early disclosure of inventions. This is a particularly relevant policy consideration in case law involving the utility standard under 35 U.S.C. §101. In *Brenner v. Manson*, 148 USPQ 689 (US Sup. Ct. 1966), for instance, the Supreme Court ruled that a process to produce a compound may be patented only if the compound has "substantial utility," "specific benefit ... in currently available form." Whether granting patent protection to the discovery of a new process or compound with a yet unknown practical utility would encourage prompt disclosure of inventions was one factor the Court carefully considered and to a significant extent relied upon in reaching the landmark decision. 148 USPQ at 695.

In *Nelson v. Bowler*, 206 USPQ 881 (CCPA 1980), the CCPA was confronted with a situation where the claimed compound, 16-phenoxy-substituted prostaglandin (PG), was shown to have some pharmacological activity, *i.e.*, causing changes in blood pressure in the rat blood pressure (BP) test and stimulation of smooth muscles in the gerbil colon smooth muscle stimulation (GC-SMS) test, yet no specific therapeutic use for the compound was established. In deciding the question of utility, the CCPA stated:

> Knowledge of the pharmacological activity of any compound is obviously beneficial to the public. It is inherently faster and easier to combat illness and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many as compounds as possible, we conclude that adequate proof of any such activity constitute a showing of practical utility.

Nelson, 206 USPQ at 883. The present case is analogous to *Nelson*. Because abnormal ion influx can interfere with normal olfactory transduction, compounds capable of modulating ion channels expressed in neuronal cells that participate in olfactory signaling, such as the CNG2B channels, are useful as therapeutic agents for altering

olfactory perception or for treating olfactory sensory anomalies. Assays for screening of ion channel modulators is thus beneficial to the public and the disclosure of how to perform these assays should be encouraged. The present application provides just this kind of disclosure. To hold that the present invention lacks sufficient utility under 35 U.S.C. §101 to warrant patent protection would be inconsistent with the underlying policy of case law and create a strong disincentive for researchers to disclose their inventions of this type.

7. Summary

In light of the foregoing discussion, Appellant believes that the utility rejection under 35 U.S.C. §101 is improper and should be withdrawn.

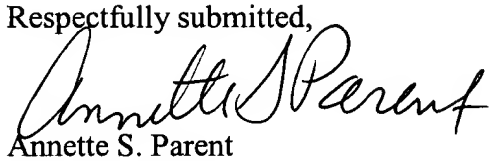
B. The Rejection for Inadequate Enablement Based on Utility Is Improper

The Examiner has also rejected claims 1, 4, 8, 19, and 20 as not being enabled, alleging that the claimed invention is not supported by either a credible specific and substantial asserted utility or a well-established utility. As discussed above, the claimed invention has a credible specific and substantial utility. Appellant therefore believes that the enablement rejection under 35 U.S.C. §112, first paragraph, is improper and should be withdrawn.

VIII. CONCLUSION

In view of the foregoing, Appellant believes all claims now pending in this Application are in condition for allowance.

Respectfully submitted,



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APPENDIX: PENDING CLAIMS

1. (Previously presented) An isolated nucleic acid encoding a polypeptide comprising a subunit of a cation channel, the polypeptide:

(i) forming, with at least one cyclic nucleotide gated cation channel (CNG) alpha subunit, a cation channel having the characteristic of cyclic nucleotide-gating; and

(ii) comprising an amino acid sequence of SEQ ID NO:1.

2. (Canceled)

3. (Previously presented) The nucleic acid of claim **1**, wherein the nucleic acid comprises a nucleotide sequence of SEQ ID NO:2 or SEQ ID NO:3.

4-7. (Canceled)

8. (Previously presented) An isolated nucleic acid encoding a cyclic nucleotide gated cation channel (CNG) 2B polypeptide, the nucleic acid comprising a nucleotide sequence of SEQ ID NO:2 or SEQ ID NO:3, or encoding a polypeptide comprising an amino acid sequence of SEQ ID NO:1.

9-18. (Canceled)

19. (Previously presented) An expression vector comprising the nucleic acid of claim **1**.

20. (Original) A host cell transfected with the vector of claim **19**.

21-40. (Canceled)